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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,863	08/20/2003	Jonathan C. Heller	29191-707	7685
21971	7590	04/19/2005	EXAMINER DEJONG, ERIC S	
WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 943041050			ART UNIT 1631	
DATE MAILED: 04/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,863

Applicant(s)

HELLER ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17-27 and 29-43 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,11-13,21,32-37,39,40 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-10,14,15,17-20,22-27,29-31,38,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3-15,17-27 and 29-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4 Sheets
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 18 March 2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The response filed by applicant on 18 March 2005 containing arguments directed to the previous Office action and an amended set of claims is acknowledged. In applicants' Remarks, filed 18 March 2005, page 6, second full paragraph, applicants have incorrectly cited the pending claims as only being those currently under examination. For the benefit of applicants, notice is given that all withdrawn claims are also "pending", though not currently under examination.

Claims 2, 16, and 28 are canceled. Claims 4-6, 11-13, 21, 32-37, 39, 40, and 43 are withdrawn from consideration. Claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 are currently under examination.

Claim Objections

The objection under 37 CFR 1.75 is hereby withdrawn due to amendments made to the instant claims.

New Matter / Claim Rejections - 35 USC § 112, First Paragraph

The rejection of claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 under 35 U.S.C. 112, first paragraph, is hereby withdrawn due to amendments made to the instant claims.

Indefiniteness / Claim Rejections - 35 USC § 112, Second Paragraph

The rejection of claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to amendments made to the instant claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, 7-10, 14, 15, 17-20, 22-24, 29-31, 38, and 42, rejected under 35 U.S.C. 102(a) as being clearly anticipated by Olek et al. is withdrawn due to amendments made to the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olek et al. in view of Fouillet et al. This rejection is reiterated from the previous office action.

Applicants argue that Olek et al. fails to disclose the following 4 limitations of amended claim 1:

- (1) Olek et al fails to teach the limitation for "without regards to a specific identity of at least some of said mass spectral components" of step (b),
- (2) Olek et al. fails to teach the limitation "the identity of a plurality of said more than 15 markers is not known" of step (c),
- (3) Olek fails to teach the limitation of "a disposable microfluidics device" of step (d), and
- (4) Olek et al. fails to teach the limitation of "in a computer system identifying the differences in case samples and control samples using said plurality of said more than 15 markers" of step (e).

Applicants further cite paragraphs 0060, 0068, 0089, 0090, 0101, 0102, and 0104 from Olek et al. in support of the argument that the teaching of Olek et al. fails to meet the above 4 limitations. In regards to the obviousness rejection of the instant claims on the basis of U.S.C. 103(a), applicants assert that the Olek et al.-Fouillet et al references fail to teach at least 3 of the above 4 limitations.

In regards to applicants assertion that limitations (1) and (2) are not taught by Olek et al., the previous office action stated on page 8, lines 13-17, "... Olek et al. teaches that the disclosed invention has applications in the global analysis of cellular proteins which is a key area of research" and referenced Olek et al., paragraphs 0005 and 0006. Lines 3-8 from paragraph 0005 of Olek et al. states "(p)roteomics uses a combination of sophisticated techniques including two-dimensional (2D) gel electrophoresis, image analysis, mass spectrometry, amino acid sequencing, and bio-

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informatics to resolve comprehensively, to quantify, and to characterize proteins.” and cites Chambers et al. and is relied upon as an explanation of mass spectroscopic techniques and practices that are intended by Olek et al. for use with the disclosed invention.

In regards to protein characterization and identification in the context of mass spectroscopy, page 283, column 1, line 26 through column 2, line 5 of Chambers et al. states:

“The tryptic masses are then evaluated using a peptide-mass fingerprinting tool such as MS-Fit, Mascot, or Peptide Search. These tools try to ‘fit’ a user’s mass spectrometry data to a protein sequence in an existing database and thus suggest the identity of the protein. This form of protein identification will only be successful if the protein being analysed is represented in the databases. For proteins which have incomplete sequence information, it is necessary to obtain sequence information for the protein by Edman degradation or by nanoelectrospray mass spectrometry. This sequence information can then be used along with the mass spectrometry information to interrogate expressed sequence tag databases.”

Thus, Chambers et al. demonstrates that the use of “fingerprinting tools” which allow a user to “try to fit” mass spectrometry data to a protein sequence is a common approach that is established and well known by those of skill in the art. Thus the mass spectral analysis presented by Olek et al. necessarily involves the process of taking mass spectroscopy data containing markers that are initially unknown and, after attempts to “try to fit” the data to known protein patterns, establish the identity of at least some or all of the peaks present in a given data set. Under a reasonably broad interpretation, such practices can be construed to mean that prior to any attempt of “trying to fit” the data to known protein patterns, the identity of all mass spectral components are not known. Therefore, any mass spectral component identified by Olek

et al. necessarily was first obtained without regards to the specific identity of at least some of the markers since all markers had to be identified after the acquisition of the data. Thus, the limitation of step (b), wherein mass spectral components are obtained without regard to a specific identity of at least some of said mass spectral components, is encompassed by the teaching of Olek et al.

Chambers et al. further demonstrates that fitting mass spectroscopy data to known protein sequences is dependant upon the existing databases for the protein under investigation and in circumstances where "...proteins which have incomplete sequence information, it is necessary to obtain sequence information for the protein". This demonstrates that it is well known in the art for proteins with incomplete sequence information, it is not possible to identify all mass spectroscopic markers obtained. Thus, the Chambers et al. document further explains the practices disclosed by Olek et al. and accommodates the limitation of step (c), wherein the identity of a plurality of said more than 15 markers is not known. As emphasis, Chambers et al. provides additional demonstrations regarding mass spectroscopic techniques as applied to specific examples of the analysis of mass spectral components wherein some spectral components cannot be completely identified. See Chambers et al., page 284, column 1, lines 38-50; page 284, column 2, lines 42-56; and page 285, column 1, lines 1-14.

In regards to applicants assertion that limitation (3) is not taught by Olek et al., the combination of the microfluidics device, as taught by Fouillet et al., taken in view of the methods taught by Olek et al. are clearly disposable taken in the reasonably broad interpretation that they are capable of being disposed. Further, as cited in the previous

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Office action on page 6, second full paragraph, Fouillet et al. teaches that "the microfluidics device is semi-disposable and, in combination with a permanent device, is relatively inexpensive" and still reads on the claimed limitation of a disposable microfluidics device.

In regards to applicants assertion that limitation (4) is not taught by Olek et al. Applicants arguments are not found convincing as Olek et al. clearly teaches in paragraph 0058 that "(a) further object of the invention is to provide systems, methods and computer program products for performing any of the inventive methods."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDJ EDS

Ardin H. Marschel 4/17/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER